

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC)	
)	
)	
Plaintiffs,)	
)	C.A. No. 06-286-GMS
v.)	
)	
BARR LABORATORIES, INC.)	
)	
Defendants.)	

JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Court's Scheduling Order (D.I. 23), plaintiffs, Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC, and defendant Barr Laboratories, Inc. respectfully submit this Joint Claim Chart in preparation for the claim construction hearing scheduled for October 31, 2007 at 9:30 a.m.

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THE '573 PATENT

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
1. An aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 45-50, 55; col. 1, line 64-65) ('573 FH, paper 4, pp. 8-10; '573 FH, paper 6, pp. 2-3; '573 FH, paper 14, pp. 1-2).	A water-based combination of ingredients that includes a medicament (col. 3, line 45)
which is capable of being sprayed into the nasal cavity of an individual	<p>The composition can be sprayed into the nasal cavity of a human being.</p> <p>The nasal cavity includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).¹</p>	
and which comprises:	Including at least the following elements:	
(A) a pharmaceutically effective amount of solid particles of triamcinolone acetonide which is effective in treating an abnormal bodily condition by virtue of its being present on the mucosal surfaces of the nasal cavity; and	<p>An amount of solid particles of triamcinolone acetonide that treats an abnormal bodily condition if it is in contact with the mucosal surfaces of the nasal cavity (col. 3, lines 59-62).</p> <p>"Triamcinolone acetonide" is a glucocorticoid the structure of which is identified at, for example, entry 9671 of The Merck Manual (13th ed. 2001).</p>	

¹ For the terms that are not contested, a jointly proposed construction is provided.

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
	<p>A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 34-35).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).</p>	<p>A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms caused by the abnormal bodily condition (col. 3, lines 59-62, 65-67)</p> <p>The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, lines 41-53; col. 11, lines 15-18; 573 FH, paper 4, p. 13)</p>
(B) a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition the following thixotropic properties:	<p>An amount of excipient that maintains the solid triamcinolone acetonide particles dispersed uniformly in the composition and causes the composition to have the thixotropic properties described below. (col. 5, lines 25-30)</p> <p>"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).</p>	<p>The specific thixotropic properties are described in the claim at (i)-(iii). ('573 FH, paper 4, pp. 10-12)</p>
(i) the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein;	<p>the viscosity of the composition at rest during non-use is sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition (col.4, line 67 – col. 5, line 2) ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)</p> <p>"Relatively high" viscosities range from about 400 to about 1000 cps when measured by the method</p>	<p>At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is higher than the shear viscosity and sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 9; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).</p>

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
	disclosed in the specification. (col. 4, line 40-41; col. 5, lines 10-24).	
(ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and	<p>upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions (col. 4, line 41-53; col. 5 lines 8-9) ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)</p> <p>"Relatively low" viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification. (col. 4, line 40-41; col. 5, lines 10-24).</p>	As the composition is shaken, the composition has a shear viscosity (or, viscosity when shaken) that becomes lower than the setting viscosity and becomes sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 9; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).
(iii) in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucociliary forces which are present in the nasal cavity.	<p>upon cessation of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucociliary forces, (col. 4, line 66 – col. 5, line 6), and reverts to the viscosity in unsheared form. (col. 4, line 63 – col. 5, line 6). See also ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)</p> <p>"Mucociliary forces" are those that cause mucociliary clearance. (col. 1, lines 50-57).</p>	Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 9; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).
2. The composition of claim 1	A composition meeting all of the limitations of claim 1	
wherein said composition includes microcrystalline	the composition includes microcrystalline cellulose and carboxymethyl cellulose sodium and a chelating agent. (col. 5, lines 32-34; col. 6, lines 34-37).	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
cellulose and carboxymethyl cellulose sodium and a chelating agent.		
3. The composition of claim 2	A composition meeting all of the limitations of claims 1 and 2	
wherein said chelating agent is disodium ethylene diamine tetraacetate.	The composition includes disodium ethylene diamine tetraacetate. (col. 6, lines 40-42).	
4. The composition of claim 2.	A composition meeting all of the limitations of claims 1 and 2	
wherein said composition includes dextrose.	The composition includes dextrose. (col. 6, lines 50-54).	
5. An aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 45-50, 55; col. 1, line 64-65) ('573 FH, paper 4, pp. 8-10; '573 FH, paper 6, pp. 2-3; '573 FH, paper 14, pp. 1-2).	A water-based combination of ingredients that includes a medicament (col. 3, line 45)
which is capable of being sprayed into the nasal cavity of an individual	The composition can be sprayed into the nasal cavity of a human being. The nasal cavity includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).	
which is odorless	Odors that cause the user discomfort are absent.	
propellant-free	It contains no agent that acts as a propellant, which is a necessary ingredient for a pressurized aerosol product. (col. 3, line 49-53).	
and has a pH of about 4.5 to about 7.5	A pH falling within the range of approximately 4.5 to approximately 7.5 (col. 6, lines 58-62).	
and which comprises:	Including at least the following elements:	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
(A) at least about 85 wt. % of water;	The composition contains at least approximately 85 percent by weight of water. (col. 3, lines 55-58)	
(B) about 0.001 to about 2 wt. % of solid particles of triamcinolone acetonide medicament;	The composition contains approximately 0.001 to approximately 2 percent by weight of solid particles of triamcinolone acetonide medicament (col. 3, lines 59-62; col. 4, lines 1-5, 24-27)	
(C) about 1 to about 5 wt. % of a suspending agent comprising a mixture of about 85 to 95 wt. % of microcrystalline cellulose and about 5 to about 15 wt. % of carboxymethyl cellulose based on the weight of the mixture, the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the composition and to impart to the composition the following thixotropic properties:	The composition contains approximately 1 to approximately 5 percent by weight of a suspending agent comprising a mixture of approximately 85 to 95 percent by weight of microcrystalline cellulose and approximately 5 to approximately 15 percent by weight of carboxymethyl cellulose, the amount of excipient being effective to maintain the solid triamcinolone acetonide particles dispersed uniformly in the composition and to cause the composition to have the thixotropic properties described below. (col. 5, lines 25-30)	
	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).	The specific thixotropic properties are described in the claim at (i)-(iii). ('573 FH, paper 4, pp. 10-12)
(i) the viscosity of the composition in unsheared form is about 400 to about 800 cp;	the viscosity of the composition at rest during non-use is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 10-24). See also ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)	The composition has a setting viscosity (or, viscosity at rest) that is approximately 400 to approximately 800 cp under certain testing conditions. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 24; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH paper 4, pp. 8-13, 17-18).
(ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 cp and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the	upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to become sprayable in the form of a fine mist that can infiltrate and deposit on mucosal surfaces (col. 4, line 41-53), and is about 50 to about 200 centipoise when measured according to the method disclosed in the specification (col. 5, lines 10-24). See also ('573 FH, paper 4, pp. 8-10, 18;	As the composition is shaken, the composition has a shear viscosity (or, viscosity when shaken) that is approximately 50 to approximately 200 cp under certain testing conditions, and is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
nasal cavity; and	<p>'573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 34-35).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).</p>	<p>nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 24; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).</p>
(iii) in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 cp and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity; and	<p>upon cessation of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases sufficiently to allow the composition to be retained on the mucosal surfaces on which it is deposited and to resist being swept away by mucocillary forces. (col. 4, line 66 – col. 5, line 6), and reverts to the viscosity in unsheared form (col. 4, line 63 – col. 5, line 6), which is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 10-24). See <i>also</i> ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2).</p> <p>"Mucocillary forces" are those that cause mucocillary clearance. (col. 1, lines 50-57).</p>	<p>Upon immediate contact with the mucosal surfaces, the composition has a setting viscosity (or, viscosity at rest) that is approximately 400 to approximately 800 cp, under certain testing conditions, and is sufficiently high to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocillary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 24; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).</p>
(D) about 0.004 to about 0.02 wt. % of a quaternary ammonium compound that has anti-microbial properties; and	The composition contains approximately 0.004 to approximately 0.02 percent by weight of a quaternary ammonium compound that protects the composition from microbial contamination and growth (col. 6, lines 15-16, 44-47)	
(E) about 0.01 to about 0.5 wt. % of a chelating agent.	The composition contains approximately 0.01 to approximately 0.5 percent by weight of a chelating agent. (col. 6, lines 35-36, 44-47).	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
6. A composition according to claim 5	A composition meeting all of the limitations of claim 5	
wherein said quaternary ammonium compound is benzalkonium chloride	wherein the quaternary ammonium compound is benzalkonium chloride (col. 6, lines 15-20, 41-47)	
and said chelating agent is disodium ethylenediamine tetraacetate.	and the chelating agent is disodium ethylenediamine tetraacetate. (col. 6, lines 41-47).	
7. A composition according to claim 5	A composition meeting all of the limitations of claim 5	
having about 0.001 to about 0.01 wt. % of dispersing agent which is effective in wetting the particles of medicament.	The composition contains approximately 0.001 to approximately 0.01 percent by weight of a dispersing agent, which functions to wet the particles of medicament. (col. 5, lines 50-62)	
8. A composition according to claim 7	A composition meeting all of the limitations of claims 5 and 7	
wherein said dispersing agent is Polysorbate 80™.	The composition contains Polysorbate 80™ (sorbitan polyoxyethylene sorbitan monooleate) as a dispersing agent, which functions to wet the particles of the medicament. (col. 5, lines 50-62; col. 6, lines 2-4).	
9. A composition according to claim 5	A composition meeting all of the limitations of claim 5	
including dextrose.	The composition contains dextrose (col. 6, lines 50-54).	
10. The composition of claim 5	A composition meeting all of the limitations of claim 5	
wherein said solid particles of medicament have an average size of about 1 to about 20 microns.	The triamcinolone acetonide particles in the composition have an average size of approximately 1 to approximately 20 microns. (col. 4, lines 14-19).	
21. A method for treating allergic rhinitis in an individual	A method to treat the symptoms of allergic rhinitis, which is an abnormal bodily condition that involves inflammation of the mucous membranes of the nose caused by allergens. (col. 1, lines 11-28).	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
<p>comprising</p> <p>applying to the mucosal surfaces of the nasal cavities of an individual a composition according to claim 5</p>	<p>Including at least the following steps</p> <p>Applying or depositing to the mucosal surfaces of the nasal cavity a composition meeting all of the limitations of claim 5 (col. 1, lines 33-35)</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51; col. 2, lines 47-63)).</p>	
	<p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 34-35).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).</p>	<p>The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, lines 41-53; col. 11, lines 15-18; 573 FH, paper 4, p. 13)</p>
<p>by spraying a dose of the composition into each of the nasal cavities of the individual,</p>	<p>The method requires that a dose of the composition be sprayed into each of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the conchas. (col. 4, lines 41-51)</p>	
<p>said dose containing a pharmaceutically effective amount of said medicament and</p>	<p>The dose contains an amount of triamcinolone acetonide that exerts its pharmacological action if it is in contact with the mucosal surfaces of the nasal cavity (col. 3, lines 20-22, 59-62, 65-67; col. 1, lines 6-38, 43-44; col. 4, lines 20-21; '573 FH, paper 4, p. 8-10, and 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p. 9; '573 FH, paper 14, pp. 1-2).</p> <p>A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)</p>	<p>The dose contains a "pharmaceutically effective amount" of triamcinolone acetonide, which is an amount that exerts pharmacological action and provides relief of nasal symptoms of allergic rhinitis (col. 3, lines 59-62, 65-67)</p>
<p>depositing pharmaceutically effective amounts of the</p>	<p>The sprayed dose infiltrates and deposits an amount of triamcinolone acetonide on each of the mucosal surfaces of anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal</p>	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
medicament on each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the conchas and	surfaces which overlie the turbinates covering the conchas (col. 3, lines 59-62, 65-67; col. 1, lines 6-38; col. 2, lines 47-63; col. 4, lines 41-53; col. 11, lines 15-18; '573 FH, paper 4, p. 8-10, 13, and 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p. 9; '573 FH, paper 14, pp.1-2)	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms of allergic rhinitis (col. 3, lines 59-62, 65-67)
such that pharmaceutically effective amounts of the medicament are retained on each of said mucosal surfaces for at least about an hour.	An amount of triamcinolone acetonide is retained on each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the concha for approximately an hour or more. (col. 1, lines 5-38; col. 3, lines 21-26; col. 4, lines 59-62; '573 FH, paper 4, p. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p. 9; '573 FH, paper 14, pp.1-2)	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms of allergic rhinitis (col. 3, lines 59-62, 65-67)
22. A method according to claim 21	A method meeting all of the limitations of claims 5 and 21	
wherein said quaternary ammonium compound is benzalkonium chloride	wherein the quaternary ammonium compound is benzalkonium chloride (col. 6, lines 15-20, 41-47).	
and said chelating agent is disodium ethylenediamine tetraacetate.	and the chelating agent is disodium ethylenediamine tetraacetate. (col. 6, lines 41-47)	
23. A method according to claim 21	A method meeting all of the limitations of claims 5 and 21	
wherein the composition which is applied to said surfaces includes about 0.001 to about 0.01 wt. % of dispersing agent which is effective in wetting the particles of medicament.	The composition contains approximately 0.001 to approximately 0.01 percent by weight of a dispersing agent, which functions to wet the particles of medicament. (col. 5, lines 50-62).	

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24. A method according to claim 23	A method meeting all of the limitations of claims 5, 21, and 23	
wherein said dispersing agent is Polysorbate 80™.	The composition contains Polysorbate 80™ (sorbitan polyoxyethylene sorbitan monooleate) as a dispersing agent, which functions to wet the particles of the medicament. (col. 5, lines 50-62; col. 6, lines 2-4).	
26. A method according to claim 21	A method meeting all of the limitations of claims 5 and 21	
wherein said composition is applied once daily to each of the nasal cavities of the individual in an amount which includes about 100 to about 130 mcg of said medicament.	The composition used in the method is applied one time per day to each of the two nasal cavities of the individual at a dose of approximately 100 to 130 mcg per nasal cavity (col. 7, lines 35-40; col. 10, line 66 – col. 11, line 6).	
27. A method according to claim 26	A method meeting all of the limitations of claims 5, 21, and 26	
wherein said composition is applied by use of a precompression pump.	The composition is applied by use of a precompression pump.	
	A "precompression pump" sprays a full dosage of a pre-selected amount of composition and will not actuate until a threshold hydraulic pressure is reached, such threshold pressure being sufficient for atomization of the spray (col. 2, lines 64-65; col. 8, lines 39-63).	
28. The method according to claim 26	A method meeting all of the limitations of claims 5, 21, and 26	
wherein said composition comprises triamcinolone acetonide, a mixture of microcrystalline cellulose and carboxymethyl cellulose sodium, Polysorbate 80™, disodium ethylenediamine tetraacetate, benzalkonium chloride, dextrose and purified water.	The composition includes at least triamcinolone acetonide, a mixture of microcrystalline cellulose and carboxymethyl cellulose sodium, Polysorbate 80™ (sorbitan polyoxyethylene sorbitan monooleate), disodium ethylenediamine tetraacetate, benzalkonium chloride, dextrose and purified water. (col. 3, lines 55-58, 59-62; col. 4, lines 1-5, 24-27; col. 5, lines 25-29, 32-45, 50-62; col. 6, lines 2-4, 15-20, 40-47, 50-54	

'573 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
29. A method of treatment according to claim 21	A method meeting all of the limitations of claims 5 and 21	
wherein said allergic rhinitis is seasonal allergic rhinitis.	The allergic rhinitis to be treated in the method is an abnormal body condition that involves inflammation of the mucous membranes of the nose that is caused by allergens that are present in the air at specific times during the year. (col. 1, lines 11-24).	
30. A method of treatment according to claim 21	A method meeting all of the limitations of claims 5 and 21	
wherein said allergic rhinitis is perennial allergic rhinitis.	The allergic rhinitis to be treated in the method is an abnormal body condition that involves inflammation of the mucous membrane of the nose that is caused by allergens that are present in the environment year-round. (col. 1, lines 11-16, 25-27).	
34. A method for applying solid particles of triamcinolone acetonide to the mucosal surfaces of the nasal cavities	A method for applying solid particles of triamcinolone acetonide particles to the mucosal surfaces of the nasal cavities.	
	<p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 34-35).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).</p>	The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things,, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 40-47; col. 2, lines 47-63; col. 4, lines 41-53; col. 11, lines 15-18; '573 FH, paper 4, p. 13).
comprising	including at least the following steps	
spraying a dose of an aqueous pharmaceutical composition containing said medicament into each of the nasal cavities,	<p>The method requires that a dose of an aqueous pharmaceutical composition be sprayed into each of the nasal cavities of a human being.</p> <p>The nasal cavity includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 47-51).</p>	
	An aqueous pharmaceutical composition is a water-based combination of ingredients	An aqueous pharmaceutical composition is a water-based combination of ingredients that includes a medicament (col.

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	comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 45-50, 55; col. 1, line 64-65) ('573 FH, paper 4, pp. 8-10; '573 FH, paper 6, pp. 2-3; '573 FH, paper 14, pp. 1-2).	3, line 45)
said dose containing a pharmaceutically effective amount of triamcinolone acetonide,	"Triamcinolone acetonide" is a glucocorticoid the structure of which is identified at, for example, entry 9671 of The Merck Manual (13 th ed. 2001).	
	<p>The dose contains an amount of triamcinolone acetonide that exerts its pharmacological action if it is in contact with the mucosal surfaces of the nasal cavity (col. 3, lines 20-22, 59-62, 65-67; col. 1, lines 6-38, 43-44; col. 4, lines 20-21; '573 FH, paper 4, p. 8-10, and 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p. 9; '573 FH, paper 14, pp. 1-2).</p> <p>A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)</p>	The dose contains a "pharmaceutically effective amount" of triamcinolone acetonide, which is an amount that exerts pharmacological action and provides relief of nasal symptoms of an abnormal bodily condition (col. 3, lines 59-62, 65-67)
said composition including also a suspending agent in an amount which is effective in maintaining said particles dispersed uniformly in the composition and in imparting to the composition thixotropic properties	The composition contains an amount of excipient that maintains the solid triamcinolone acetonide particles dispersed uniformly in the composition and causes the composition to have thixotropic properties. (col. 5, lines 25-30).	
	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An	The suspending agent causes the composition to have the thixotropic properties described as follows. At rest, the composition is a gel with a setting viscosity (or viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear

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	Introduction to Rheology, p. 168).	viscosity (or, viscosity when shaken) that becomes lower than the setting viscosity and sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity. That setting viscosity is sufficiently high to maintain particles of medicament suspended therein and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocilliary forces present in the nasal cavity as described below. (col. 1, lines 10-15, 41-47; col. 2, line 47-63; col. 4, line 27 - col. 5, line 9; col. 11, line 15-18; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18)
such that pharmaceutically effective amounts of triamcinolone acetonide are deposited on each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses, and on each of the mucosal surfaces which overlie the turbinates covering the conchas and	The sprayed dose infiltrates and deposits an amount of triamcinolone acetonide on each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses, and on each of the mucosal surfaces which overlie the turbinates covering the conchas (col. 3, lines 59-62, 65-67; col. 1, lines 6-38; col. 2, lines 47-63; col. 4, lines 41-53; col. 11, lines 15-18; '573 FH, paper 4, p. 8-10, 13, and 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p. 9; '573 FH, paper 14, pp.1-2)	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms of an abnormal bodily condition (col. 3, lines 59-62, 65-67)
such that portions of said amounts are retained on each of said mucosal surfaces for at least about an hour.	Portions of the deposited pharmaceutically effective amounts of triamcinolone acetonide are retained on each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the concha for approximately an hour or more. (col. 1, lines 5-38; col. 3, lines 22-26; col. 4, lines 59-62)	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 3, lines 59-62)	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms of an abnormal

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		bodily condition (col. 3, lines 59-62, 65-67)
35. A method according to claim 34	A method meeting all of the limitations of claim 34	
wherein the viscosity of the composition in unsheared form is about 400 to about 1000 centipoises	the viscosity of the composition at rest during non-use is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 10-24) ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)	The viscosity of the composition before shear is applied and upon immediate contact with the mucosal surfaces of the nasal cavity (i.e., the setting viscosity) is approximately 400 to approximately 1000 cp under certain testing conditions. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 24; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).
and wherein the viscosity of the composition when shaken is about 50 to about 200 centipoises.	upon application of shear force through shaking, the viscosity of the composition decreases sufficiently to allow the composition to become sprayable in the form of a fine mist that can infiltrate and deposit on mucosal surfaces (col. 4, line 41-53), and is about 50 to about 200 centipoise when measured according to the method disclosed in the specification (col. 5, lines 10-24) ('573 FH, paper 4, pp. 8-10, 18; '573 FH, paper 6, pp. 2-3; '573 FH, paper 13, p.9; '573 FH, paper 14, pp.1-2)	The shear viscosity (or, viscosity when shaken) of the composition is approximately 50 to approximately 200 cp under certain testing conditions. (col. 1, lines 10-15, 41-47; col. 2, lines 47-63; col. 4, line 27 – col. 5, line 24; col. 11, lines 15-18; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, pp. 8-13, 17-18).

THE '329 PATENT

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
1. An aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 54-59, 64; col. 2, line 5-6) ('327 FH, paper 3, p. 2).	A water-based combination of ingredients that includes a medicament (col. 3, line 54)
which is capable of being sprayed into the nasal cavity of an individual	The composition can be sprayed into the nasal cavity of a human being. The nasal cavity includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).	
which is propellant-free	It contains no agent that acts as a propellant, which is a necessary ingredient for a pressurized aerosol product (col. 3, line 59-63)	
and has a pH of about 4.5 to about 7.5	A pH falling within the range of approximately 4.5 to approximately 7.5 (col. 6, line 66- col. 7, line 3)	
and which comprises:	Includes at least the following elements	
(A) at least about 85 wt. % of water;	The composition contains at least approximately 85 percent by weight of water (col. 3, line 64-67)	
(B) about 0.001 to about 2 wt. % of solid particles of triamcinolone acetonide;	The composition contains approximately 0.001 to approximately 2 percent by weight of solid particles of triamcinolone acetonide medicament (col. 4, line 1-4, 10-14, 33-36)	
(C) about 1 to about 5 wt. % of a suspending agent comprising a mixture of about 85 to 95 wt. % of microcrystalline cellulose and about 5 to about 15 wt. % of carboxymethyl cellulose based on the weight of the mixture, the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the	The composition contains approximately 1 to approximately 5 percent by weight of a suspending agent comprising a mixture of approximately 85 to 95 percent by weight of microcrystalline cellulose and approximately 5 to approximately 15 percent by weight of carboxymethyl cellulose, the amount of excipient being effective to maintain the solid triamcinolone acetonide particles dispersed uniformly in the composition and to cause the composition to have the thixotropic properties described below. (col. 5, lines 41-47, 52-54)	
	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent	The specific thixotropic properties are described in the claim at (i) through (iii). ('573 FH, paper 4, pp. 10-12)

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composition and to impart to the composition the following thixotropic properties:	viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).	
(i) the viscosity of the composition in unsheared form is about 400 to about 800 centipoise;	the viscosity of the composition at rest during non-use is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 19-33). <i>See also</i> ('327 FH, paper 3, p. 2)	The composition has a setting viscosity (or, viscosity at rest) that is approximately 400 to approximately 800 cp under certain testing conditions. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 34; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
(ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 centipoise and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and	<p>Upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to become sprayable in the form of a fine mist that can infiltrate and deposit on mucosal surfaces (col. 4, line 50-62), and is about 50 to about 200 centipoise when measured according to the method disclosed in the specification (col. 5, lines 19-33). <i>See also</i> ('327 FH, paper 3, p. 2)</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).</p>	As the composition is shaken, the composition has a shear viscosity (or, viscosity when shaken) that is approximately 50 to approximately 200 cp under certain testing conditions, and is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 34; col. 11, lines 25-28; '573 FH, paper 1, pp. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
(iii) in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 centipoise and such that it resists being cleared from the mucosal surfaces by the inherent mucociliary forces which are present in the nasal cavity;	upon cessation of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases sufficiently to allow the composition to be retained on the mucosal surfaces on which it is deposited and to resist being swept away by mucociliary forces. (col. 5, lines 8-15), and reverts to the viscosity in unsheared form (col. 5,	Upon immediate contact with the mucosal surfaces, the composition has a setting viscosity (or, viscosity at rest) that is approximately 400 to approximately 800 cp, under certain testing conditions, and is sufficiently high to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time

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and	lines 5-15), which is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 19-33). <i>See also</i> ('327 FH, paper 3, p. 2). "Mucocillary forces" are those that cause mucocillary clearance. (col. 1, lines 60-65).	must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 34; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
a compound that has anti-microbial properties.	The composition contains a compound that protects the composition from microbial contamination and growth (col. 6, lines 23-24)	
3. A composition according to claim 1	A composition meeting all of the limitations of claim 1	
having about 0.001 to about 0.01 wt. % of dispersing agent which is effective in wetting the particles of medicament.	The composition contains approximately 0.001 to approximately 0.01 percent by weight of a dispersing agent, which functions to wet the particles of medicament. (col. 5, line 59 – col. 6, line 4)	
4. A composition according to claim 3	A composition meeting all of the limitations of claims 1 and 3	
wherein said dispersing agent is Polysorbate 80™.	The composition contains Polysorbate 80™ (sorbitan polyoxyethylene sorbitan monooleate) as a dispersing agent, which functions to wet the particles of the medicament. (col. 6, line 11-13)	
5. A composition according to claim 1	A composition meeting all of the limitations of claim 1	
including dextrose.	The composition contains dextrose (col. 6, line 58-61)	
6. An article of manufacture comprising	An object made by humans or machines Includes at least the following elements	
(A) an aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or	A water-based combination of ingredients that includes a medicament (col. 3, line 54)

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	minimize tissue irritation (col. 3, line 54-59, 64; col. 2, line 5-6) ('327 FH, paper 3, p. 2).	
which comprises:	Includes at least the following elements	
a pharmaceutically effective amount of solid particles of triamcinolone acetonide which is effective in treating an abnormal bodily condition by virtue of its being present on the mucosal surfaces of the nasal cavity and	An amount of solid particles of triamcinolone acetonide that treats an abnormal bodily condition if it is in contact with the mucosal surfaces of the nasal cavity (col. 4, lines 1-4, 7-9) "Triamcinolone acetonide" is a glucocorticoid the structure of which is identified at, for example, entry 9671 of The Merck Manual (13 th ed. 2001).	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 4, lines 1-4)	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms caused by the abnormal bodily condition (col. 4, lines 1-4, 7-9)
	"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44). The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).	The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, line 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 50-62; col. 11, line 25-28; '573 FH, paper 4, p. 13)
a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition the following thixotropic properties:	An amount of excipient that maintains the solid triamcinolone acetonide particles dispersed uniformly in the composition and causes the composition to have the thixotropic properties described below. (col. 5, lines 33-46)	
	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).	The specific thixotropic properties are described in the claim at (i) through (iii). ('573 FH, paper 4, p. 10-12).
(i) the viscosity of the composition in unsheared form is	the viscosity of the composition at rest during non-use is sufficiently high to hold and maintain	At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is higher than the shear viscosity and

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relatively high, with the composition being a gel having said particles suspended therein;	<p>the particles of medicament dispersed substantially uniformly in the composition (col. 5, lines 9-11) ('327 FH, paper 3, p. 2)</p> <p>"Relatively high" viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification. (col. 4, line 4950; col. 5, lines 19-33).</p>	sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
(ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and	<p>upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions (col. 4, line 50-62; col. 5 lines 17-18) ('327 FH, paper 3, p. 2)</p> <p>"Relatively low" viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification. (col. 4, line 49-50; col. 5, lines 19-33).</p>	As the composition is shaken, the composition has a shear viscosity (or, viscosity when shaken) that becomes lower than the setting viscosity and becomes sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
(iii) in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucociliary forces which are present in the nasal cavity;	<p>upon removal of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucociliary forces, (col. 5, line 8-15), and reverts to the viscosity in unsheared form (col. 5, line 5-15). See also ('327 FH, paper 3, p. 2)</p> <p>"Mucociliary forces" are those that cause mucociliary clearance. (col. 1, lines 60-65).</p>	Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocilliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).

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(B) a vessel which contains said composition; and	The article of manufacture includes a vessel (for example, a bottle) that contains the composition. (col. 9, lines 39-40; col. 10, lines 33-36)	
(C) a precompression pump which is associated with the vessel and which is capable of spraying a full dose of the composition into the nostril of an individual.	A "precompression pump" sprays a full dosage of a pre-selected amount of composition and will not actuate until a threshold hydraulic pressure is reached, such threshold pressure being sufficient for atomization of the spray (col. 7, lines 49-54; col. 8, line 47 – col. 9, line 3). The precompression pump is connected to the vessel containing the composition. (col. 10, lines 35-36)	
7. The article of manufacture of claim 6	An article of manufacture meeting all of the limitations of claim 6	
wherein said composition further comprises an antimicrobial compound.	The composition contains a compound that protects the composition from microbial contamination and growth (col. 6, lines 23-24)	
8. The article of manufacture of claim 6	An article of manufacture meeting all of the limitations of claim 6	
wherein said composition further comprises a chelating agent.	The composition includes a chelating agent. (col. 6, line 42-45)	
9. The article of manufacture of claim 6	An article of manufacture meeting all of the limitations of claim 6	
wherein said vessel contains greater than two full doses of said composition.	The vessel (for example, a bottle) holds three or more full doses of the composition. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-49; col. 8, lines 59-63; col. 11, lines 3-5).	
10. The article of manufacture of claim 6	An article of manufacture meeting all of the limitations of claim 6	
wherein said vessel contains a least about 120 full doses of said composition.	The vessel (for example, a bottle) holds approximately 120 or more full doses of the composition. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-49; col. 8, lines 59-63; col. 11, lines 3-5).	
11. The article of manufacture of claim 9	An article of manufacture meeting all of the limitations of claims 6 and 9	

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wherein said precompression pump is capable of spraying at least one full dose of about 100 mg of said composition into the nostril of an individual.	The precompression pump is capable of spraying one or more full doses of the composition, at approximately 100 mg each, into the nostril of an individual. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-49; col. 8, lines 59-63; col. 11, lines 3-5).	
12. The article of manufacture of claim 9	An article of manufacture meeting all of the limitations of claims 6 and 9	
wherein said precompression pump is capable of spraying at least one full dose of composition containing about 55 mcg of triamcinolone acetonide into the nostril of an individual.	The precompression pump is capable of spraying one or more full doses containing 55 micrograms of triamcinolone acetonide per spray of the composition into the nostril of an individual. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-49; col. 8, lines 59-63; col. 11, lines 3-5).	
13. An article of manufacture comprising:	An object made by humans or machines Including at least the following elements	
(A) a thixotropic	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168)	At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear viscosity (or, viscosity when shaken) that is lower than the setting viscosity and is sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to maintain the particles suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocilliary forces

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		present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
aqueous pharmaceutical composition	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 54-59, 64; col. 2, line 5-6) ('327 FH, paper 3, p. 2).	A water-based combination of ingredients that includes a medicament (col. 3, line 54)
which is capable of being sprayed into the nasal cavity of an individual	The composition can be sprayed into the nasal cavity of a human being. The nasal cavity includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 57-60).	
which is propellant-free	It contains no agent that acts as a propellant, which is a necessary ingredient for a pressurized aerosol product (col. 3, line 59-63)	
and has a pH of about 4.5 to 7.5	A pH falling within the range of approximately 4.5 to approximately 7.5 (col. 6, line 66- col. 7, line 3)	
and which comprises:	Includes at least the following elements	
(a) triamcinolone acetonide;	"Triamcinolone acetonide" is a glucocorticoid the structure of which is identified at, for example, entry 9671 of The Merck Manual (13 th ed. 2001).	
(b) a mixture of microcrystalline cellulose and carboxymethylcellulose sodium;	A mixture of microcrystalline cellulose and carboxymethylcellulose sodium (col. 5, line 41-43)	
(c) Polysorbate 80;	Polysorbate 80™ (sorbitan polyoxyethylene sorbitan monooleate) (col. 6, line 11-13)	
(d) disodium ethylenediamine tetraacetate;	disodium ethylenediamine tetraacetate (col. 6, line 49-51)	
(e) benzalkonium chloride;	Benzalkonium chloride (col. 6, line 23-29)	

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(f) dextrose; and	Dextrose (col. 6, line 58-61)	
(g) purified water;	purified water (col. 3, line 64-67)	
(B) a vessel which contains said composition; and	The article of manufacture includes a vessel (e.g., bottle) that contains the composition. (col. 9, lines 39-40; col. 10, lines 33-36)	
(C) a precompression pump associated with the vessel and which is capable of spraying a full dose of the composition into the nostril of an individual.	A "precompression pump" sprays a full dosage of a pre-selected amount of composition and will not actuate until a threshold hydraulic pressure is reached, such threshold pressure being sufficient for atomization of the spray (col. 3, lines 5-6; col. 8, line 47 – col. 9, line 3). The precompression pump is connected to the vessel containing the composition (col. 10, lines 35-36)	
14. A method for treating allergic rhinitis in an individual	A method to treat the symptoms of allergic rhinitis, which is an abnormal bodily condition that involves inflammation of the mucous membranes of the nose caused by allergens. (col. 1, lines 19-36)	
comprising	Including at least the following steps	
the administration to said individual of an aqueous thixotropic pharmaceutical composition	<p>The method includes delivering to a human patient an aqueous thixotropic pharmaceutical composition.</p> <p>An aqueous pharmaceutical composition is a water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation (col. 3, line 54-59, 64; col. 2, line 5-6) ('327 FH, paper 3, p. 2).</p> <p>"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168)</p>	<p>An aqueous pharmaceutical composition is a water-based combination of ingredients that includes a medicament (col. 3, line 54)</p> <p>The specific thixotropic properties of the aqueous pharmaceutical composition are described in the claim at (B). ('573 FH, paper 4, p. 10-12).</p>
comprising:	Including at least the following elements	

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
(A) a pharmaceutically effective amount of solid particles of triamcinolone acetonide which is effective in treating allergic rhinitis by virtue of its being present on the mucosal surfaces of the nasal cavity of the individual; and	An amount of solid particles of triamcinolone acetonide that treats allergic rhinitis if it is in contact with the mucosal surfaces of the nasal cavity (col. 4, lines 1-4, 7-9) "Triamcinolone acetonide" is a glucocorticoid the structure of which is identified at, for example, entry 9671 of The Merck Manual (13 th ed. 2001).	
	A "pharmaceutically effective amount" is one that exerts the pharmacological action of the medicament (col. 4, lines 1-4) "Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44). The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).	A "pharmaceutically effective amount" of triamcinolone acetonide is an amount that exerts pharmacological action and provides relief of nasal symptoms caused by allergic rhinitis (col. 4, lines 1-4, 7-9) The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 50-62; col. 11, line 25-28; '573 FH, paper 4, p. 13)
(B) a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition thixotropic properties;	The composition contains an amount of excipient that maintains the triamcinolone acetonide particles dispersed uniformly in the composition and causes the composition to have the thixotropic properties described below. (col. 5, lines 32-45)	
	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).	The specific thixotropic properties are described below. ('573 FH, paper 4, p. 10-12).
by spraying a full dose of the composition in the form of a readily flowable atomized mist into one of the nostrils of the individual for deposit on the mucosal	The method requires that a full dose of the composition be sprayed into one of the nostrils of the individual. (col. 4, lines 41-51)	
	A "full dose" is the volume of dose sprayed through actuation of the precompression pump.	The volume of dose of the composition sprayed through actuation of the precompression pump is sprayed into the

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
surfaces of the nasal cavity in the form of a viscous composition which resists being cleared from the mucosal surfaces by the inherent mucociliary forces which are present in the nasal cavity.	<p>(col. 1, lines 57-58; col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-49; col. 8, lines 59-63; col. 11, lines 3-5).</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44, col. 4, lines 54-60).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).</p> <p>"Mucociliary forces" are those that cause mucociliary clearance. (col. 1, lines 61-65)</p>	nostril of the individual and deposits on the mucosal surfaces of the nasal cavity. At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear viscosity (or, viscosity when shaken) that is lower than the setting viscosity and is sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine atomizable mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to maintain the particles suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
15. The method of claim 14	A method meeting all of the limitations of claim 14	
wherein said administration of said composition is performed once daily.	The composition is administered once daily (col. 7, lines 37-49)	
16. The method of claim 15	A method meeting all of the limitations of claims 14 and 15	

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wherein said once-a-day administration includes spraying multiple full doses of said composition.	The once a day administration includes spraying more than one volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 8, line 47 – col. 9, line 3; col. 11, lines 3-5, 12-15).	
17. The method of claim 14	A method meeting all of the limitations of claim 14	
wherein said composition resists being cleared from the mucosal surfaces for at least one hour.	<p>The composition resists being cleared from the mucosal surfaces for at least one hour.</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44).</p>	<p>Amounts of the composition resist being cleared from each of the mucosal surfaces of the nasal cavity for an hour or more. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55- col. 3, line 4; col. 3, lines 30-34; col. 4, lines 50-62; col. 5, lines 1-4; col. 11, lines 25-28; '573 FH, paper 4, p. 13)</p>
22. The method of claim 14	A method meeting all of the limitations of claim 14	
comprising spraying a total of about 100 to about 130 mcg of said triamcinolone acetonide into said nostril of said individual daily.	The composition used in the method is applied one time per day to each of the two nasal cavities of the individual at a dose of approximately 100 to approximately 130 mcg per nasal cavity. (col. 7, lines 45-48; col. 11, lines 3-10)	
23. The method of claim 14	A method meeting all of the limitations of claim 14	
comprising spraying a full dose of about 55 mcg of said triamcinolone acetonide into said nostril of said individual.	The composition used in the method is applied to each of the two nasal cavities of the individual at a full dose of approximately 55 mcg of triamcinolone acetonide. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 8, line 48 – col. 9, line 3; col. 11, lines 3-10).	
24. The method of claim 23	A method meeting all of the limitations of claim 23	
including spraying two of said full doses into said nostril once-a-day.	The composition used in the method is applied to each of the two nasal cavities of the individual by spraying two full doses. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 8, line 48 – col. 9, line 3; col. 11, lines 3-10).	
25. A method for delivering an	A method for delivering a water-based	A method for delivering an aqueous thixotropic

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
<p>aqueous thixotropic pharmaceutical composition comprising triamcinolone acetonide to each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the conchas</p>	<p>combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation to the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the concha (col. 4, lines 54-60; col. 3 lines 54-59, 55; col. 2, line 5-6) ('327 FH, paper 3, p. 2).</p> <p>The composition contains triamcinolone acetonide medicament.</p> <p>The sprayed dose infiltrates and deposits amounts of triamcinolone acetonide that treats an abnormal bodily condition by exerting pharmacological action when in contact with the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses and on each of the mucosal surfaces which overlie the turbinates covering the concha (col. 4, lines 54-60) ('327 FH, paper 3, p. 2).</p> <p>"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An Introduction to Rheology, p. 168).</p>	<p>pharmaceutical composition with TAA to each of the mucosal surfaces of the anterior regions of the nose, the frontal and maxillary sinuses and on each of the mucosal surfaces of the turbinates covering the conchas in amounts sufficient to treat allergic rhinitis. The composition has the following properties. The composition is a water-based combination of ingredients that includes a medicament. At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear viscosity (or, viscosity when shaken) that is lower than the setting viscosity and is sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest). That setting viscosity is sufficiently high to maintain the particles suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. The "mucosal surfaces of the nasal cavity" are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).</p>
comprising	Includes at least the following steps	

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
spraying a full dose of the composition in the form of a readily flowable atomized mist into each nostril of the individual and	The composition used in the method is applied to each of the two nasal cavities of the individual by spraying a full dose in the form of a readily flowable atomized mist. A "full dose" is the volume of dose sprayed through actuation of the precompression pump. (col. 3, lines 5-6; col. 7, lines 37-48; col. 8, lines 17-22; col. 8, lines 48-63; col. 11, lines 3-10).	
allowing said sprayed composition to deposit on said surfaces in the form of a viscous composition which resists being cleared from the mucosal surfaces by the inherent mucocilliary forces which are present in the nasal cavity.	<p>When sprayed in each nostril, it deposits on the mucosal surfaces of the nasal cavity and resists being cleared by mucocilliary forces.</p> <p>"Mucosal surfaces" are bodily tissues which line the nasal cavity. (col. 1, lines 41-44).</p> <p>The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities (col. 4, lines 56-60).</p> <p>"Mucocilliary forces" are those that cause mucocilliary clearance. (col. 1, lines 61-65)</p>	<p>The composition when sprayed in the nasal cavity is deposited on each of the mucosal surfaces of the anterior regions of the nose, the frontal and maxillary sinuses and on each of the mucosal surfaces of the turbinates covering the conchas. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity (or, viscosity at rest) that is higher than the shear viscosity and sufficiently high to maintain the medicament suspended in the composition and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucocilliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 19; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).</p>
26. The method of claim 25	A method meeting all of the limitations of claim 25	
wherein said composition comprises about 1 to about 5 wt. % of a suspending agent comprising a mixture of about 85 to 95 wt. % of microcrystalline cellulose and about 5 to about 15 wt. % of carboxymethyl cellulose based on the weight of the mixture, the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the composition and to	<p>The composition contains approximately 1 to approximately 5 percent by weight of a suspending agent comprising a mixture of approximately 85 to 95 percent by weight of microcrystalline cellulose and approximately 5 to about 15 percent by weight of carboxymethyl cellulose, the amount of excipient being effective to maintain the solid triamcinolone acetonide particles dispersed uniformly in the composition and to cause the composition to have the thixotropic properties described below. (col. 5, lines 34-39)</p> <p>"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed. (HA Barnes, JF Hutton, and K Walters, An</p>	<p>The specific thixotropic properties are described in the claim at (i) through (ii). ('573 FH, paper 4, p. 10-12).</p>

'329 PATENT CLAIM LANGUAGE	AVENTIS'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
impart to the composition the following thixotropic properties:	Introduction to Rheology, p. 168).	
(i) the viscosity of the composition in unsheared form is about 400 to about 800 centipoise;	The viscosity of the composition at rest during non-use is about 400 to about 800 centipoise when measured according to the method disclosed in the specification (col. 5, lines 19-33). <i>See also</i> ('327 FH, paper 3, p. 2)	The viscosity of the composition before shear is applied and upon immediate contact with the mucosal surfaces of the nasal cavity (i.e., the setting viscosity) is approximately 400 to approximately 800 cp under certain testing conditions. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 34; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).
(ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 centipoise.	Upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to become sprayable in the form of a fine mist that can infiltrate and deposit on mucosal surfaces (col. 4, line 50-62), and is about 50 to about 200 centipoise when measured according to the method disclosed in the specification (col. 5, lines 19-33). <i>See also</i> ('327 FH, paper 3, p. 2)	The shear viscosity (or, viscosity when shaken) of the composition is approximately 50 to approximately 200 cp under certain testing conditions. (col. 1, lines 19-25, 49-55; col. 2, line 55 – col. 3, line 4; col. 4, line 37 – col. 5, line 34; col. 11, lines 25-28; '573 FH, paper 1, p. 9-11; '573 FH, paper 4, p. 8-13, 17-18).